



UNITED STATES PATENT AND TRADEMARK OFFICE

COMMISSIONER FOR PATENTS
UNITED STATES PATENT AND TRADEMARK OFFICE
P.O. BOX 1450
ALEXANDRIA, VA 22313-1450
www.uspto.gov

FOLEY AND LARDNER LLP
SUITE 500
3000 K STREET NW
WASHINGTON DC 20007

COPY MAILED

DEC 15 2009

In re Patent No. 7,521,451
Issued: April 21, 2009
Application No. 10/534,414
Filing or 371(c) Date: May 11, 2005
Dkt. No.: 074129-0521

: **OFFICE OF PETITIONS**
: **PATENT TERM ADJUSTMENT**
:
:

This is a decision on the “REQUEST FOR RECONSIDERATION OF PATENT TERM ADJUSTMENT UNDER 37 CFR 1.705,” filed April 24, 2009. This matter is being properly treated under 37 CFR 1.705(d).

Patentees request correction of the patent term adjustment from 404 days to 764 days. Patentees requested this correction on the basis that the Office took in excess of three years to issue the above-referenced patent. Patentees also contest the holding set forth in the Letter mailed March 16, 2009.

The application for patent term adjustment (PTA) under 37 CFR 1.705(d) is **DISMISSED**.

The above-identified application matured into U.S. Pat. No. 7,521,451 on April 21, 2009. The patent issued with a patent term adjustment of 404 days. The instant application for patent term adjustment was timely filed in accordance with 37 CFR 1.705(d). Applicants argue that in view of Wyeth v. Dudas, 580 F. Supp. 2d 138, 88 U.S.P.Q. 2d 1538 (D.D.C. 2008), the patent is entitled to an adjustment of 764 days (442 days pursuant to 35 USC 154(b)(1)(A) *plus* 345 days pursuant to 35 USC 154(b)(1)(B) *less* 23 days of applicant delay).

Patentees assert that the Office indicated that the date of commencement of the instant application is July 27, 2006 in a Letter mailed March 16, 2009. This assertion is in error as the Letter mailed March 16, 2009 set forth that July 27, 2006 is the date upon which adjustment pursuant to 37 CFR 1.702(a)(1) *commenced*.

Patentees further request that the “15 day reduction taken with the mailing of the Letter Regarding PTA mailed March 16, 2009, was in error.” Patentees are again advised that the period of adjustment pursuant to 37 CFR 1.702(a)(1) is found to be 427 days and not 442 days. Accordingly, the calculation was adjusted by removing 15 days of PTA delay to net an overall adjustment of 404 days (442 days of adjustment pursuant to 37 CFR 1.702(a)(1) *less* 23 days of applicant delay *equals* 404 days).

In accordance with 37 CFR 1.702(a)(1), an application is subject to patent term adjustment for the Office’s failure to mail at least one of a notification under 35 U.S.C. 132 or a notice of

allowance under 35 U.S.C. 151 not later than fourteen months after the date on which the application was filed under 35 U.S.C. 111(a) or fulfilled the requirements of 35 U.S.C. 371 in an international application. The instant application fulfilled the requirements of 35 USC 371 on May 26, 2005, as indicated on the Notice of Acceptance of Application under 35 USC 371 and 37 CFR 1.495 mailed November 3, 2005.

An application does not per se fulfill the requirements of 35 USC 371 upon the *receipt* of the 35 USC 371(c)(1), (c)(2), and (c)(4). An application fulfills the requirements of 35 USC 371 upon the *latest* of:

- (A) the date of submission of the basic national fee;
- (B) the date of submission or communication of the copy of the international application;
- (C) the date of submission of the translation of the international application if the international application is not in the English language;
- (D) the date of submission of an oath or declaration of the inventor in compliance with 35 U.S.C. 371 (c)(4) (see 37 CFR 1.497(c) for an explanation of when an oath or declaration will be accepted as complying with 35 U.S.C. 371(c)(4));
- (E) the earlier of 30 months from the priority date or the date of request for early processing under 35 U.S.C. 371(f) if requested prior to 30 months from the priority date (Form PCT/DO/EO/903 will indicate the date early processing was requested);
- (F) if a request for early processing has not been requested prior to 30 months from the priority date, the date of submission of any translation of the annexes to the international preliminary examination report if the translation of the annexes are filed within the time period set in a Notification of Missing Requirements (Form PCT/DO/EO/905) requiring either an English translation of the international application or an oath or declaration; and
- (G) the date of submission of any surcharge for submitting the oath or declaration later than 30 months from the priority date.

See, MPEP 1893.03(b).

Thus, in accordance with 37 CFR 1.703(a)(1), the period of adjustment of 427 days pursuant to 37 CFR 1.702(a)(1) commenced July 27, 2006 and ended September 26, 2007, the date that the restriction requirement was mailed.

Accordingly, the request for restoration 15 days of adjustment is hereby DISMISSED.

Patentees further argue that the “commencement date of the present application is 14 months from the date of receipt of all requirements under 35 USC 371, which was July 11, 2006.” This calculation is in error, as discussed herein.

As to patentees request for an additional adjustment of 345 days pursuant to 37 CFR 1.702(b), patentees are advised that under 37 CFR 1.703(f), patentees are entitled to a period of patent term adjustment equal to the period of delays based on the grounds set forth in 37 CFR 1.702 reduced by the period of time equal to the period of time during which patentees failed to engage in reasonable efforts to conclude prosecution pursuant to 37 CFR 1.704. In other words, patentees are entitled to the period of Office delay reduced by the period of applicant delay.

The Office asserts that as of the issuance of the patent on April 21, 2009, the application was pending three years and 330 days after the national stage commenced under 35 U.S.C. 371(b) or (f) in an international application. The commencement date is the date 30 months from the earliest priority date claimed in the international application. In this application, the earliest priority date claimed, as shown on the Notice of Acceptance of Application Under 35 U.S.C. § 371 and 37 CFR 1.495, mailed November 3, 2005, is November 26, 2002. Accordingly, the commencement date is May 26, 2005, and the period of adjustment pursuant to 37 CFR 1.703(b) began May 27, 2008, the day after the date that is three years after the date that national stage commenced, and ended April 21, 2009, the date that the patent issued, or 330 days.

The Office asserts that certain action was not taken within the specified time frame, and thus, the adjustment of 427 days pursuant to 37 CFR 1.702(a)(1) is correct. At issue is whether patentees should accrue 330 days of patent term adjustment for the Office taking in excess of three years to issue the patent, as well as 427 days for Office failure to take a certain action within a specified time frame (or examination delay).

The Office contends that the period of 330 days of delay in issuance of the patent under 37 CFR 1.702(b) overlaps with the period of 427 days of examination delay under 37 CFR 1.702(a)(1). Patentees' calculation of the period of overlap is inconsistent with the Office's interpretation of this provision. 35 U.S.C. 154(b)(2)(A) limits the adjustment of patent term, as follows:

35 U.S.C. 154(b)(2)(A) limits the adjustment of patent term, as follows:

To the extent that the periods of delay attributable to grounds specified in paragraph (1) overlap, the period of any adjustment granted under this subsection shall not exceed the actual number of days the issuance of the patent was delayed.

As explained in *Explanation of 37 CFR 1.703(f)¹ and of the United States Patent and Trademark Office Interpretation of 35 U.S.C. 154(b)(2)(A)*, 69 Fed. Reg. 34283 (June 21, 2004), the Office interprets 35 U.S.C. 154(b)(2)(A) as permitting either patent term adjustment under 35 U.S.C. 154(b)(1)(A)(i)-(iv), or patent term adjustment under 35 U.S.C. 154(b)(1)(B), but not as permitting patent term adjustment under both 35 U.S.C. 154(b)(1)(A)(i)-(iv) and 154(b)(1)(B). Accordingly, the Office implements the overlap provision as follows:

If an application is entitled to an adjustment under 35 U.S.C. 154(b)(1)(B), the entire period during which the application was pending (except for periods excluded under 35 U.S.C. 154(b)(1)(B)(i)-(iii)), and not just the period beginning three years after the actual filing date of the application, is the period of delay under 35 U.S.C. 154(b)(1)(B) in

¹ Likewise, 37 CFR 1.703(f) provides that:

To the extent that periods of delay attributable to the grounds specified in §1.702 overlap, the period of adjustment granted under this section shall not exceed the actual number of days the issuance of the patent was delayed.

determining whether periods of delay overlap under 35 U.S.C. 154(b)(2)(A). Thus, any days of delay for Office issuance of the patent more than 3 years after the filing date of the application, which overlap with the days of patent term adjustment accorded prior to the issuance of the patent will not result in any additional patent term adjustment. See 35 U.S.C. 154(b)(1)(B), 35 U.S.C. 154(b)(2)(A), and 37 CFR § 1.703(f). See *Changes to Implement Patent Term Adjustment Under Twenty Year Term; Final Rule*, 65 Fed. Reg. 54366 (Sept. 18, 2000). See also *Revision of Patent Term Extension and Patent Term Adjustment Provisions; Final Rule*, 69 Fed. Reg. 21704 (April 22, 2004), 1282 Off. Gaz. Pat. Office 100 (May 18, 2004).

Further, as stated in the *Explanation of 37 CFR 1.703(f) and of the United States Patent and Trademark Office Interpretation of 35 U.S.C. 154(b)(2)(A)*, the Office has consistently taken the position that if an application is entitled to an adjustment under the three-year pendency provision of 35 U.S.C. 154(b)(1)(B), the entire period during which the application was pending before the Office (except for periods excluded under 35 U.S.C. 154(b)(1)(B)(i)-(iii)), and not just the period beginning three years after national stage commenced, is the relevant period under 35 U.S.C. 154(b)(1)(B) in determining whether periods of delay “overlap” under 35 U.S.C. 154(b)(2)(A).

This interpretation is consistent with the statute. Taken together the statute and rule provide that to the extent that periods of delay attributable to grounds specified in 35 U.S.C. 154(b)(1) and in corresponding §1.702 overlap, the period of adjustment granted shall not exceed the actual number of days the issuance of the patent was delayed.

In this instance, the relevant period under 35 U.S.C. 154(b)(1)(B) in determining whether periods of delay “overlap” under 35 U.S.C. 154(b)(2)(A) is the period during which the application was pending before the Office beginning on the date that national stage commenced under 35 U.S.C. 371(b) or (f) in an international application, May 26, 2005, and ending on the date that the patent issued, April 21, 2009.

Pursuant to 35 U.S.C. 154(b)(1)(A) and 37 CFR 1.702(a)(1), 427 days of examination delay accrued prior to issuance of patent. Pursuant to 35 U.S.C. 154(b)(1)(B) and 37 CFR 1.702(b), the application was pending three years and 330 days prior to the issuance of the patent on April 14, 2009.

The 330 days of delay in issuance of the patent under 37 CFR 1.702(b) overlap with the 427 days of patent term adjustment under 37 CFR 1.702(a)(1). Entry of both the 330 days and the 427 days is neither permitted nor warranted given that 427 days is the actual number of days issuance of the patent was delayed.

Accordingly, at issuance, having considered the 330 days of Office delay under the three-year pendency provision in conjunction with the 427 days of examination delay, reduced 23 days for applicant delay, the Office properly entered 404 days of patent term adjustment.

In view thereof, no adjustment to the patent term will be made.

Receipt is hereby acknowledged to be required \$200.00 patent term adjustment application fee.
37 CFR 1.18(e).

Telephone inquiries specific to this matter should be directed to the undersigned at (571) 272-3205.



Alesia M. Brown
Petitions Attorney
Office of Petitions